



**National Patent
Analytical Systems, Inc.**

Mr. Robert Drawbaugh
Vermont Dept of Health
Box 70
Burlington, Vt. 05402-0700

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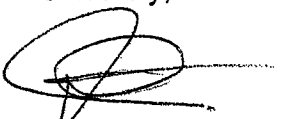
Dear Mr. Drawbaugh:

Regarding your request for clarification of our warranty policy: We do have a stated 2 year warranty on DataMaster Products, including the DMT. However, we have always considered the warranty to start upon actual deployment of the instruments to the field rather than the shipping date when multi instrument state orders are involved. Further, since the placement of the instruments is often staggered in time, we usually pick a mutually agreeable date that reflects, more or less, an average placement date. This is easier and more convenient for all concerned. This is not a policy that was ever reduced to written form and probably never will be but it certainly is helpful to our customers. The only caveat is that the warranty maintenance, repairs and recalibrations be done by a technician who has been certified by us as a maintenance technician.

Regarding the issue of your technician using parts from one of our demonstrator or loaner instruments to repair an instrument from your inventory. If it is helpful to your program we certainly support this remedy. We can send you a replacement part for the loaner instrument and your technician can install it.

Our records currently indicate that your employee Steve Harnois is certified by us to perform maintenance and recalibrations on the DataMasters and DMT instruments. Given his experience and level of expertise, it is my opinion that he should perform the maintenance on the new DMT instruments.

Sincerely,



John Fusco,
President

Calibration, Certification & Installation of DataMaster DMTs

1. Calibration:

a. Calibration Simulator (Calibration Solution)

- i. Open new bottle of Calibration Solution ~ 0.10 EtOH, or
- ii. Used bottle if open less than one week or not used more than 20 times.
- iii. Record solution temperature (requirement = $34^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$)

b. Calibration Simulator (Blank)

- i. Use laboratory prepared Milli-Q
- ii. Record solution temperature (requirement = $34^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$)

c. Calibration Simulator (External Standard)

- i. Prepare using ~ 0.1 EtOH External Standard Solution
- ii. Record solution temperature (requirement = $34^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$)
- iii. Initiate Accuracy & Precision test

iv. Requirements:

1. Average must be $\pm 3\%$ of certified value
2. Standard deviation must be ≤ 0.002
3. calibration factor for b2 must be $0.002 \leq b2 \leq 0.012$

d. Documentation

- i. Record on DataMaster Calibration Logbook (ALC 668)
- ii. If problems, record in Testing Notebook for initial testing or initiate DataMaster Technical Support Inquiry (TSI) if initial testing complete.

2. Certification:

a. Certification Solutions

- i. Replace Quarterly or when solution falls out of acceptance criteria
- ii. Record solution temperature (requirement = $34^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$)

b. Documentation

- i. Record in DataMaster Certification Solution Information logbook

c. Procedure

Calibration, Certification & Installation of DataMaster DMTs

- i. Follow DataMaster prompts – each linearity check solution is analyzed as seven replicates. Perform R^2 statistical analysis.
- ii. Lowest linearity check standard must be $\pm 10\%$ of nominal value and remaining three standards must be $\pm 5\%$
- iii. Supply sample breaths as prompted by the DataMaster.

3. Installation:

- a. Fill simulator with Simulator Solution ~ 0.100 EtOH; attach Simulator Solution label to head of simulator
- b. Accuracy & Precision test is part of installation - five replicates are analyzed.

i. Requirements

1. Average must be $\pm 5\%$ of certified value
2. Standard deviation must be < 0.002

ii. Documentation

1. File one copy of Installation Report to onsite maintenance records
2. Second copy is peer reviewed and filed in room # 124.
3. Affix second simulator solution label to DataMaster Maintenance Logbook (ALC 803); include name, date of installation and any corrective action documentation.
4. In the DataMaster Operators Logbook (ALC 603) document name and results of simulator solution average